STATEMENT OF WORK – CIRB INITIATIVE

Background:

The Central Institutional Review Board (CIRB) Initiative is a project of the National Cancer Institute (NCI) to develop and implement a centralized model of Institutional Review Board review for multi-site, NCI-sponsored clinical trials. The goal of the Initiative is two-fold:

A. To decrease the duplicative burden of full-board protocol review that currently occurs at hundreds of local IRBs nationwide by providing a single centralized review that can be utilized by local IRBs participating in NCI-sponsored multi-center trials.

B. To maintain, and perhaps enhance, the protection of research participants by providing consistent, expert IRB review of NCI-sponsored clinical trials before the trial receives final NCI approval.

Currently, the Initiative involves two Boards, one reviewing adult multi-site, NCI-sponsored clinical trials and the other reviewing pediatric trials coordinated by the Children's Oncology Group (COG). There are over 315 enrolled local IRBs who can use the CIRB review materials to conduct their own facilitated review. Under the facilitated review mechanism, the local IRB no longer is required to conduct a full Board review to approve a multi-site, NCI-sponsored clinical trial; instead, the local IRB chair or designated subcommittee reviews all the CIRB documents for any local concerns and accepts or rejects the CIRB review. The local facilitated review process can take hours or days instead of weeks.

The NCI recruits and appoints individuals to serve on the CIRB. The adult CIRB has been providing reviews since January 2001. The pediatric CIRB began reviewing studies in 2004. Both Boards will be meeting twice a month. Originally, the adult Board was meeting once a month in Bethesda however in an effort to decrease the travel burden on CIRB members while increasing the frequency of meetings, a web-based meeting tool called ePanel© was implemented and is currently being used. ePanel© was developed by another NCI contractor and allows the meetings to be convened via an internet-assisted conference call (please see http://www.webtie.org). Board members conference call into the meeting from a location convenient to them while using the internet-based meeting facilitator. In-person meetings, designed to provide training and to facilitate interactions, are conducted twice yearly in Bethesda.

For more detailed background information on the CIRB Initiative including a roster of participating sites, information on how to join, more details on facilitated review and Board members, etc., please visit the CIRB website at the following URL http://www.ncicirb.org.

Scope:

The purpose of this contract is to provide an on-going comprehensive support for two functioning IRBs (one for adult trials and the other for pediatric trials) as well as facilitate new site enrollments and provide support for existing local IRBs participating in the Initiative. In addition, the Contractor will facilitate the NCI's efforts to promote the expansion of the Initiative to approximately 600 additional sites currently conducting NCI

Cooperative Group trials. The Contractor shall be responsible for the following tasks:

Task 1: Manage and provide administrative and regulatory support for two Central IRBs, one for adult trials and one for pediatric trials

Task 2: Manage and support current and newly enrolled local sites

Task 3: Support the recruitment of new sites and conduct their integration into the Initiative

Task 4: Provide informatics systems to support all operations

Task 5: Support communications with NCI and stakeholders regarding all aspects of the Initiative

Task 6: Implement and manage an Initiative-wide Quality Improvement Plan

Optional work:

Option 1: Provide support for obtaining Association for Accreditation of Human Research Protection Programs, Inc. (AAHRPP) accreditation in contract year 1 or 2, as determined by NCI.

Option 2: Establish and maintain informatics to support Board meeting responsibilities.

Option 3: Manage and support an additional adult CIRB, if required, as a result of expanding the pool of trials reviewed by the CIRB

Option 4: Enhance and update CIRB Initiative informatics system to ensure compliance with the cancer Biomedical Informatics Grid (caBIG) principles

Option 5: Develop and implement a system for utilizing central review for sites that do not have a local IRB.

As these tasks indicate, the Contractor's responsibilities are more complex than the standard management of two central IRBs. One unusual feature of this Initiative is that every decision the CIRBs make have an impact on the NCI's trial development and distribution system; consequently, all Standard Operating Procedures (SOPs) must be integrated with the relevant administrative procedures of the NCI's Protocol Information Office (PIO) in the Cancer Therapy Evaluation Program (CTEP), the Cancer Trials Support Unit (CTSU), and the Cooperative Groups' Operations offices. In addition, due to the high profile of this Initiative, sophisticated data management, analysis and presentation are required throughout all activities in Tasks 1-6. The Contractor must be prepared on a frequent and often unscheduled basis to provide data to NCI on the current status of any and all activities.

Uniform Assumptions

For the purpose of estimating costs, the following uniform assumptions should be made:

1. There will be approximately 310-350 local sites enrolled in the CIRB Initiative when the contract begins; the remaining approximately 600 sites conducting Cooperative Group trials will be actively solicited for enrollment.

2. A restricted-access website is maintained and populated by the Contractor to include all documents and correspondence associated with a CIRB review. Local IRB and research staff consult the website to obtain the documents required to perform a facilitated review. For 2007, the monthly median of the number of documents posted to the website is 331. The public side of the website is located at the following URL www.ncicirb.org.

3. The helpdesk is experiencing a current volume of approximately 100 queries a month.

4. Approximately 30 new institutions are enrolled in the CIRB Initiative annually.

5. There are a minimum of five conferences (e.g., PRIMR/ARENA, AAHRPP, and Cooperative Group meetings) a year, which Contractor staff will need to attend. Three will be located in the St. Louis area and two will be located in the San Diego area.

6. Adult and pediatric CIRB meetings are conducted twice a month. In addition, there may be a need to conduct ad hoc meetings to handle urgent issues, with little prior notice.

7. Except for approximately 2 in-person meetings each year, CIRB meetings are conducted via an internet-enhanced conference call using a system named ePanel© developed under NCI contract by Humanitas, (please see http://www.webtie.org). The CIRB Contractor is responsible for providing Humanitas with review documents to post in advance of the meeting as well as obtaining a conference call number for the meeting. Between July 2005 and October 2007, there were 4,358 documents posted on ePanel© involving 1,342 studies. Humanitas provides the technical support for ePanel© before, during and after each meeting.

8. On average, the adult Board will review approximately 25 new Cooperative Group phase 3 studies per year. It is possible that Phase 2 adult studies (of which there are about 100 new annually) will gradually be added to the menu.

9. The pediatric Board will review approximately 30 new studies each year including pediatric Phase 2, Phase 3 and pilots.

10. Currently there are 155 studies on the CIRB menu for which local IRBs can perform a facilitated review and approximately 15 studies which are CIRB-approved and awaiting activation by the coordinating Cooperative Group. There have been 5,828 facilitated reviews performed as of 10/03/2007.

11. Each Board will have approximately 16 members, including an AE Subcommittee that reviews adverse events weekly.

12. There have been 1,602 adverse events reviewed between October 2005 and October 2007.

13. The Contractor's staff and the activities related to carrying out the tasks in the

Statement of Work shall be referred to the "CIRB Initiative Operations Office".

14. The Contractor will be expected to attend bi-weekly meetings at the Cancer Therapy Evaluation Program offices in Rockville, Maryland.

15. The number of physician practices without a local IRB, if this option is exercised, would be, at most, 10 per year.

Statement of Work:

The Contractor shall furnish all services, qualified personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed, to perform the Central Institutional Review Board (CIRB) Initiative tasks set forth below:

TASK 1: <u>Manage and provide administrative and regulatory support for two Central Institutional Review Boards (one for adult trials and the other for pediatric trials).</u>

For each CIRB, the Contractor shall:

A. Provide support for scheduled (twice a month) and occasional unscheduled, ad-hoc CIRB meetings, including all administrative tasks involved in the preparation, conduct and follow-up of meeting actions (includes managing expedited review). These tasks include, but are not limited to, the following:

1. Receipt of all CIRB required documentation from the NCI's Cancer Therapy Evaluation Program's (CTEP) Protocol Information Office (PIO), the Division of Cancer Prevention's PIO, and the Cooperative Groups.

2. Review documents for completeness; resolve if incomplete.

3. Assign reviewers for each review to be conducted, including initial review, continuing review and amendment review.

4. Arrange for Study Chair and CTEP disease therapeutic leads to be on call for each item on the meeting agenda.

5. Arrange for a conference call line for each regularly scheduled and ad hoc Board meeting.

6. Assign reviewers for Serious Adverse Events (SAE) documents that are received from CTEP or the Cooperative Groups, forward those documents to the SAE subcommittee reviewer then ensure that their recommendations are posted on ePanel© for the next CIRB meeting of the appropriate Board.

7. Coordinate, prepare and distribute agendas for all meetings.

8. Coordinate, prepare and distribute meeting packets including agenda and related review materials to Board members per their preferred receipt method: email, CD, FedEx, other.

9. Submit all meeting documents via email to the NCI Contractor responsible for maintenance of the CIRB ePanel©. NOTE: The current Contractor, Humanitas, is located near Bethesda, Maryland.

10. Take detailed minutes of regular Board meetings, ad-hoc Board meetings, ad-hoc SAE subcommittee meetings and ad-hoc Conflict of Interest (COI) subcommittee meetings. Expediently prepare and obtain Board approval for minutes of each meeting.

11. Prepare all CIRB correspondence related to meeting review outcomes, including, but not limited to, drafting outcome letters, including approvals, requests for clarifications and disapprovals, and sending the drafted letters to the Chair for signature(s) then distributing the letters to appropriate Study Chairs and Cooperative Group staff in a timely manner.

12. Communicate with the Chair, Board members and ePanel© staff via telephone and electronic mail, as necessary, to ensure smooth operations.

13. For in-person meetings, provide travel and lodging arrangements for members and speakers, secure a meeting location and obtain Project Officer approval of such, arrange for light refreshments, meals and local transportation for Board members and speakers, prepare and distribute handouts.

14. Prepare and distribute meeting honorarium payments for Board members and Chairs.

B. Maintain and update yearly the SOPs guiding Board and the CIRB Initiative Operations Office functions. The Contractor shall ensure that all SOPs are in compliance with federal laws and regulations, and that all administrative activities and Board actions are in compliance with the SOPs. Current SOPs are included in this solicitation as an attachment.

C. Plan, organize and conduct continuing education programs for CIRB members, including, individual new member orientations, new chair orientations, AE subcommittee orientations, bi-monthly briefings at all meetings and an annual Education Day/Workshop, as per the Office of Human Research Protections (OHRP) requirements. Arrange for board members to receive Hasting's Report or similar periodical as part of their continuing education activities. Develop and maintain continuing education records for each member.

D. Record attendance and completion of primary reviewer assignments per

Board member; manage conflict of interest, recusal and meeting quorum issues prior to and during all meetings; provide support to the NCI in selecting members, including tracking tenure and categories of members as well as creating a database for potential appointees. Gather or prepare short biosketches for each Board member and post on the CIRB website.

E. With the direction of NCI, purchase and hold professional liability insurance for Board members without gaps in coverage at time of renewal.

TASK 2: <u>Manage and support current and newly enrolled local sites</u>

The Contractor shall:

A. Maintain a current roster of enrolled signatory institutions as well as tracking of a new site's progress through the enrollment process. The roster should include names of local IRBs, their affiliated IRBs and research sites and contact information for each.

B. Maintain a current roster of local IRBs who have performed a facilitated review, including but not limited to, date of performance of facilitated review, related study, local IRB staff entering the facilitated review via the website, local PI name and contact information.

C. Maintain and update, as needed, all features of the public side of the CIRB website (www.ncicirb.org) to reflect current status and provide helpful information including Frequently Asked Questions. Maintain and update, at least weekly, the private side of the website, posting all CIRB-reviewed study-specific information at the appropriate time. The entire website should reflect an intuitive, attractive and user-friendly design.

D. Maintain the functionality of the website's facilitated review acceptance form

E. Provide continuing support to new and enrolled sites as they interface with the CIRB, including the following:

1. Provide a help-desk with knowledgeable staff to answer any questions and concerns as they are presented to the help desk. The help desk should consist of telephone, voicemail, and electronic mail capabilities. The help-desk shall be staffed and the phone answered by a person between 8:00AM and 4:00PM, E.S.T., with voice-mail provided during non-working hours.

2. Maintain an interaction tracking log of phone calls and electronic mailings, detailing and categorizing requests and their related responses; provide a summary of the tracking log to the PO on a monthly basis.

3. Create and distribute electronic updates of website postings to all email addresses of enrolled sites on a bi-weekly basis.

4. Update the 'Frequently Asked Questions' section of the website as well as the look and feel of the public side of the website, as necessary, to provide a comprehensive and instructional tool for stakeholders as well as those interested in the Initiative.

5. Create an instructional manual for local institutional staff, Cooperative Group staff, and PIO staff to provide guidance regarding their interactions with and responsibilities to the CIRB Initiative and Operations Office.

F. Educate local investigators and local IRB staff on all current and new procedures.

G. Develop, maintain and revise, as necessary, all SOPs for interactions pertaining to local sites.

H. Coordinate the flow of information between the CIRB, the Cancer Trials Support Unit (please see http://www.ctsu.org) and COG, as directed by NCI, to assure smooth functioning of the regulatory requirements for enrolling patients on trials available via the CTSU and COG. This will include, but not be limited to, the following:

1. Supplying lists of CIRB sites that have accepted facilitated review.

2. Documenting the network of sites that utilize a single, local IRB's use of a facilitated review.

3. Developing a user-friendly annual renewal process to confirm continued participation in the Initiative.

TASK 3: <u>Support the recruitment of new sites and facilitate their integration into the CIRB Initiative.</u>

The Contractor shall:

A. Support CTEP's execution of a recruitment and integration plan for the Cooperative Group sites that have not yet enrolled in the CIRB Initiative. The new sites will include, but not be limited to, the Bone Marrow Consortium sites, Cooperative Group affiliated US sites and Phase 2 contract sites.

B. Develop and maintain a database for tracking (including date, method and content) of all recruitment activities including interactions with local institutional officials, research staff and IRB staff; then provide an activity report on a monthly basis to the Project Officer.

C. Develop, maintain and revise, as necessary, SOPs for the integration of new sites into the Initiative's processes and database.

D. Assist sites in the CIRB enrollment process.

E. After sites have enrolled, assist them in developing local procedures for

interfacing with the CIRB.

F. Enhance existing and/or develop new promotional materials (e.g., brochures, flyers, meeting booths and advertisements) for recruitment, enrollment and facilitation of local site integration into the Initiative.

G. Support public relations activities, such as:

1. Maintaining and revising/developing, as necessary, text for the public side of the website.

2. Attend an occasionally make presentations at approximately five conferences each year.

3. Setting up and staffing exhibit booths/tables.

4. Assisting the NCI staff in the development and conduct of presentations.

5. Assist the NCI staff with identifying local institutional representatives, institutional officials, and both local IRB and research staff who can serve as representing the population of CIRB users to prospective sites.

6. Conduct post-conference/presentation follow-up, such as correspondence or evaluation surveys, as requested by the PO or designee.

TASK 4: <u>Provide informatics systems to support all operations</u>

The Contractor shall:

A. Maintain and enhance, as necessary, the current CIRB system for reporting and tracking study-related activity as well as tracking local site activity, to include, but not be limited to, the following data:

1. <u>Studies</u>

a. Group ID number
b. Study title with ability to query key words
c. Name of Study Chair
d. Contact information of the Study Chair
e. NCI Protocol Version Date
f. All Board actions (with dates) for each study
   i. Initial review with immediate, intermediate and final outcomes, when applicable.
   ii. Amendment review with immediate, intermediate and final outcomes, when applicable.
   iii. Adverse event review with immediate, intermediate and

final outcomes, when applicable.

iv. Continuing review with immediate, intermediate and final outcomes, when applicable.

v. Reviews of miscellaneous documents, such as recruitment materials, including outcomes of all reviews, when applicable.

2. Participating Sites

a. Signatory institution profile

i. Name

ii. Contact information for IRB and research staff

iii. Date of enrollment

iv. Description (NCI-designated cancer center, Community Clinical Oncology Program (CCOP), academic or community site)

v. Studies and dates when facilitated review has been utilized by local IRB for that study

vi. Local IRB(s) on the signatory's assurance

- Contact information
- Description as above (iv)
- Federal-wide Assurance number
- IRB Organization Number
- Affiliated local IRBs (relying on the signatory IRB)
  - Contact information
  - Description as above (iv)
  - IRB Organization Number

b. Investigators with potential to enroll a subject into a study at an institution using facilitated review, including:

i. Contact information

ii. Cooperative Group affiliation

3. Maintain a site/investigator log that can be queried by criteria or keywords such as state, city, Group affiliation, or use of facilitated review by specific study.

B. Develop, when directed by the Project Officer and where appropriate and feasible, links between the CIRB database and other related activities, such as the CTSU regulatory database and CTEP databases.

C. Maintain the current public and private sides of the CIRB website, as needed, including, but not limited to, the following tasks:

1. Posting all documents and hyperlinks related to study review and activity.

2. Updating the CIRB website to incorporate timely dissemination of information, as necessary or when specifically requested by the

Project Officer.

D. Maintain a security plan for all informatics activities, including routine data backup and recovery.

E. Provide routine reports to the PO, which include, but are not limited to, the following types:

1. Reports of data gathered in Task 4, A.

2. Primary Reviewer List: a listing of all active Board members who have served as a Primary Reviewer for one or more studies, including associated dates of review.

3. Study Activity Summary List: a study-specific listing with dates of all Group and CIRB reviews and correspondence from initial submission to final report at time of termination.

4. List of Study Chair Potential Conflicts: a listing of all Study Chairs, their declared conflict of interests and the coordinating Cooperative Group's management plan of the conflict

5. Studies due for annual renewal: a listing of studies and the dates when they are scheduled for continuing review based on their initial review date or last continuing review date. Listing includes the date which is 6 weeks preceding the study's expiration date which represents the date by which the CIRB must have the study approved for continuation and the continuing review documents must posted on the website.

6. Abbreviated list of studies: a listing of all studies by ID number and title including initial review dates, the final outcome of the first full Board initial review, the current status of the study and the Group study activation date, if applicable.

TASK 5: <u>Support communications with NCI and stakeholders regarding all aspects of the Initiative.</u>

The Contractor shall:

A. Provide organized and detailed project management leadership including support of the following activities:

1. Meet with the NCI team on a bi-weekly basis. Generate the agenda and minutes of all bi-weekly Contractor-NCI team meetings, providing project calendars with deliverable dates and development timelines.

2. Provide monthly data updates via reports and PowerPoint slides as determined by the Project Officer, for example:
    a. Screen shot of website public slide home page
    b. Screen shot of website log-in screen to private side
    c. Pediatric CIRB member composition by category
    d. Adult CIRB member composition by category
    e. Summary of study-specific reviews
    f. Updated list of NCI-designated cancer centers enrolled in the Initiative (including city and state)
    g. Updated list of CCOPs whose primary IRB is enrolled in the Initiative (including city and state)
    h. Updated list of academic centers enrolled in the Initiative (including city and state)
    i. Number of sites and investigators, listed by Cooperative Group, enrolled in the Initiative
    j. Local IRB (LIRB) enrollment by quarter
    k. Cumulative number of facilitated review acceptances, by quarter
    l. Use of facilitated review, by month, for the last twelve months
    m. Column graph, comparing by year - LIRB enrollment with use of facilitated review.
    n. A slide illustrating the number of enrolled institutions, the total number of LIRBs enrolled and the number of LIRBs accepting at least one facilitated review
    o. Bar graph illustrating the number of studies on the CIRB menu, per Cooperative Group, and the use of facilitated review for each Cooperative Group's studies
    p. Group-specific slides illustrating the following data points:
        i. The total number of the Group's studies on the CIRB menu and the number of facilitated reviews accepted for each.
        ii. The total number of facilitated reviews accepted per institution with institutions arranged by Cooperative Group affiliation and facilitated reviews grouped by numerical categories
        iii. Screenshot of each Cooperative Group's studies on the menu
        iv. The total number of facilitated reviews accepted by each Group's sites
        v. The number of facilitated reviews accepted for a Cooperative Group’s studies by other Group's sites
    q. Additional reports, requested by NCI, that are retrievable from data gathered in Task 4.

3. Quick response to unplanned, time-sensitive requests from NCI for data or other information.

B. Maintain effective communications with the Cooperative Groups Operations Offices, including participating in standing meetings and teleconferences, developing, maintaining and updating "how-to" handbooks and developing other communications methods, as needed.

C. Maintain effective communications with relevant CTEP Contractors/Branches/Initiatives, such as the PIO and CTSU. This includes participation in standing meetings/teleconferences, developing, maintaining and updating the "how-to" handbooks and developing other communications methods, as needed.

TASK 6: <u>Implement and manage an Initiative-wide Quality Improvement Plan.</u>

The Contractor shall:

A. Develop (in collaboration with the PO), implement and manage a Quality Improvement Plan for all aspects of the Initiative. Identify Quality Improvement indicators that need to be monitored, monitor those indicators and report all results to the PO.

B. The Contractor shall obtain periodic feedback from all stakeholders including local IRBs and research staff, CTEP's PIO, and Cooperative Group staff to ascertain their satisfaction with the CIRB Initiative as well as to gather their suggestions for potential process improvements.

OPTIONAL WORK: The Contractor will provide staffing and support, as described in the optional tasks below, while integrating these practices into the existing Initiative's operational infrastructure, wherever possible.

OPTION 1: If this option is exercised, the Contractor shall provide support for obtaining Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) accreditation in contract year 1 or 2, as determined by NCI [please see http://www.aahrpp.org].

OPTION 2: If this option is exercised, the Contractor shall establish and maintain informatics to support Board meeting responsibilities such as: tracking of study submissions and status; tracking study expiration dates; tracking contact information for Study Chairs and Cooperative Groups; agenda building; customizable alerts/ticklers designed to keep processes timely; facilitating recording of minutes; and generating draft correspondence.

OPTION 3: If this option is exercised, the Contractor shall support a second board for adult trials, when NCI decides it is needed, to accommodate expanding the pool of trials reviewed by the CIRB. The Contractor shall provide staffing and support, as described in the above tasks, while integrating another board into the existing operational infrastructure.

OPTION 4: If this option is exercised, the Contractor shall provide informatics and systems integration for the CIRB Initiative. Specifically, the Contractor will enhance and update the CIRB Initiative system to ensure compliance with the cancer Biomedical Informatics Grid (caBIG) principles of open source, open development, open access and federated data. The system should leverage the cancer Data Standards Repository (caDSR) and should utilize common data elements and appropriate vocabulary services, as appropriate.

The information models for the Initiative shall be developed and maintained in a standard modeling language, such as Unified Modeling Language (UML). The system must also meet the "silver" level of caBIG compatibility, as laid out in the most recent caBIG compatibility document on the caBIG website (please see http://cabig.nci.nih.gov).

The system architecture should be scalable and support the collaborative environment (and challenges) of optimally running a CIRB. The system should be based on a three-tiered architecture for modularity, encapsulation and ease of management.

The system should provide a single-source collaboration platform supported by low-cost administrative capabilities that greatly improves the efficiencies of regulatory activities and research practices within the participating communities of the Initiative. The IRB members, staff and the research community will be able to make virtually all of their service selections from a single source web-based portal in the future. The system should provide support for collaborative functioning, such as "portal functionality", to have views specific to IRBs, protocols and meetings. The system should have integrated workflows and should allow for easy data exchange with local IRBs using well-defined Application Program Interfaces (APIs) and/or a web-services based approach.

Activities to update and enhance the system shall include an effort to analyze all current workflows and processes, reengineer them, as required, to optimize them, and where most advantageous, facilitate movement towards electronic submission, tracking and dissemination of all documents among stakeholders within a reasonable period of time. The system shall eliminate data-duplication and allow for easy information exchange. Standards, such as Health Level Seven (HL7) and Clinical Data Interchange Standards (CDISC), should be exploited for effective information exchange. Automated interfaces to ensure seamless integration with the Protocol Authorization and Tracking System (PATS), ePanel®, CTSU and other CTEP-Enterprise System (ESYS) components shall be considered integral to the success of a mature Initiative solution for the NCI.

The system should be secure and all transactions should be fully audited in a manner consistent with the needs of compliance with the Code of Federal

Regulations (CFR) 21, Part 11. Where applicable, electronic signatures shall

also meet the requirements defined by CFR 21, Part 11. As applicable to the mission of the Initiative, the Contractor shall ensure compliance with pertinent IRB related regulations including CFR 21, Part 50; CFR 21, Part 56 and CFR 45, Part 46.

The Contractor shall ensure and implement a comprehensive security program, in compliance with the current Office of Management and Budget (OMB) and National Institute of Standards and Technology (NIST) regulations. The Contractor shall utilize portal technologies to ensure that websites are seamlessly updated with built-in approval mechanisms. The CIRB system should allow and provide for mechanisms to communicate effectively with the various application stakeholders.

The Contractor shall develop a change management plan for the system, and develop and manage an ongoing risk management plan. Software development, maintenance and upgrades will be performed utilizing industry best practices and caBIG guidelines

OPTION 5: If this option is exercised, the Contractor shall develop a central review system for sites without at local IRB. For example, the CIRB could take over the entire responsibility for the site, which would include reviewing investigators and ensuring that the federal requirement for the review of local context issues is being met. Alternatively, the CIRB could elect to contract with a commercial central IRB that would fulfill the local site requirements for the CIRB while the CIRB performed the protocol reviews.